

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

COMMONWEALTH OF PENNSYLVANIA
and STATE OF NEW JERSEY,

Plaintiffs,

v.

DONALD J. TRUMP, *in his official capacity as President of the United States*; ROBERT F. KENNEDY, JR., *in his official capacity as Secretary of Health and Human Services*; UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; SCOTT BESSANT, *in his official capacity as Secretary of the Treasury*; UNITED STATES DEPARTMENT OF THE TREASURY; LORI CHAVEZ-DeREMÉR, *in her official capacity as Secretary of Labor*; UNITED STATES DEPARTMENT OF LABOR; and UNITED STATES OF AMERICA,

Defendants,

LITTLE SISTERS OF THE POOR SAINTS
PETER AND PAUL HOME,

Intervenor-Defendant.

No. 2:17-cv-04540-WB

**BRIEF IN SUPPORT OF
INTERVENOR-DEFENDANT'S
MOTION FOR SUMMARY
JUDGMENT AND IN OPPOSITION
TO PLAINTIFFS' MOTION FOR
SUMMARY JUDGMENT**

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INTRODUCTION

After a 7-2 loss on their primary claims at the Supreme Court—and a five-year delay—the States have asked this Court to rule on their second- and third-tier arguments against the Little Sisters’ religious exemption. But those arguments were weak to start, and they have been weakened further by the Supreme Court’s recognition that the agencies were “instructed” to accommodate religious exercise in the Final Rule, that the agencies were obligated to obey RFRA, and that the exemption was permissible. The States also fail to mention that the harm they envisioned has not materialized in the years since the religious exemption took effect—and that even the Biden Administration’s proposals would have kept the religious exemption intact. There is good reason the federal government never argued any of the States’ alleged constitutional and statutory conflicts in the years it spent defending the Mandate: those arguments were always inconsistent with governing law.

The States’ Article III problems have worsened too. Even now, they cannot show how enjoining the Final Rule and reinstating the prior rules would help them, or how the Final Rule harms even a single one of their citizens. They make no attempt to address the numerous injunctions forbidding the agencies from enforcing the prior rules against any sincere religious objectors—what good can this Court’s injunction do if the federal government is already enjoined from enforcing the underlying Mandate? And even though the Final Rule has been in effect for five years, they still can’t come up with a single scrap of evidence that any employer has discontinued contraceptive coverage as a result of the Final Rule. Nor have the States even *tried* to challenge the regulatory feature that actually *implements* the Final Rule—the HRSA guidelines. There is no order this Court can issue about the rules that will solve the States’ alleged problems.

As the States’ arguments have withered, the stakes have grown. The States’ persistence in this lawsuit has now squarely put not just the narrow religious exemptions at issue, but also the constitutionality of the entire contraceptive mandate. That is because the Supreme Court in *Little*

Sisters strongly implied that the entire contraceptive mandate violates the nondelegation doctrine, as Congress gave HRSA discretion to craft the Mandate without “any criteria or standards.” That “virtually unbridled discretion” also violates the Appointments Clause because it was given to HRSA, and HRSA’s Administrator has not been properly appointed as an officer of the United States under Article II because he was not approved by the Senate. Finally, the underlying Mandate violates the First Amendment, as it discriminates against objecting religious groups and reaches into the “internal management decisions” of those religious groups, upending their constitutionally-guaranteed religious autonomy under the Supreme Court’s decision in *Our Lady of Guadalupe School v. Morrissey-Berru*, 591 U.S. 732, 746 (2020). The States’ persistent attempts to take away religious exemptions thus threaten to invalidate the contraceptive mandate altogether, because neither this Court nor any other can provide the requested relief in light of these constitutional infirmities. That makes their claims unredressable too.

It is time to end the contraceptive mandate litigation, and it should not take a fourth trip to the Supreme Court to do it.

BACKGROUND

A. The Mandate and its exceptions

Federal law requires some employers (namely, those with over 50 employees) to offer group benefits with “minimum essential coverage.” 26 U.S.C. § 5000A(f); 26 U.S.C. § 4980H(a), (c)(2). That “minimum essential coverage” must include, among other things, coverage for “preventive care and screenings” for women. 42 U.S.C. § 300gg-13(a)(4); 29 U.S.C. § 1185d. Congress did not define “preventive care” in the statute. Instead, Congress delegated to the Health Resources and Services Administration (HRSA), a division of HHS, the authority to determine what should be included as preventive care “for purposes of this paragraph.” 42 U.S.C. § 300gg-13(a)(4).

HRSA issued guidelines on its website mandating coverage of all FDA-approved female contraceptive methods (the Mandate). J.A. 310-12. Through a lengthy series of interim rules and

final rules, and over the objection of many religious organizations, the federal government implemented the Mandate, as described by the Supreme Court in *Little Sisters of the Poor Saints Peter & Paul Home v. Pennsylvania*, 591 U.S. 657, 662-674 (2020).

Not all private employers are subject to this Mandate. First, the vast majority of employers—those with fewer than 50 employees—are not required to provide any insurance coverage at all.¹ Second, at the time the Final Rule was issued, approximately twenty percent of large employers were exempt through the ACA’s exception for “grandfathered health plans.” See 26 U.S.C. § 4980H(c)(2); 42 U.S.C. § 18011; 75 Fed. Reg. 34,538, 34,542 (June 17, 2010); J.A. 2176 (projection through 2017). For non-exempt employers, the penalty for offering a plan that excludes coverage for even one of the FDA-approved contraceptive methods is \$100 per day for each affected individual. 26 U.S.C. § 4980D(a)-(b). If an employer with more than 50 employees fails to offer a plan at all, the employer owes \$2,000 per year for each of its full-time employees. 26 U.S.C. § 4980H(a), (c)(1).

In response to religious objections, the agencies published an Advance Notice of Proposed Rulemaking (ANPRM), 77 Fed. Reg. 16,501 (Mar. 21, 2012), and a Notice of Proposed Rulemaking (NPRM), 78 Fed. Reg. 8456 (Feb. 6, 2013), which were later adopted in a final rule making further changes to the Mandate, 78 Fed. Reg. 39,870 (July 2, 2013). The agencies eventually amended the definition of a religious employer by eliminating some of the criteria from the Second Interim Final Rules (IFRs), limiting the definition to organizations “referred to in section 6033(a)(3)(A)(i) or (iii) of the [Internal Revenue] Code,” thus exempting “churches, their

¹ According to some estimates, more than 97% of employers have fewer than 50 employees, and therefore face no federal obligation to provide coverage at all. See, e.g., DMDatabases.com, *USA Business List – Employee Size Profile*, <https://perma.cc/5WDN-DC6U>. The *Hobby Lobby* Court estimated that “34 million workers” are employed by firms with fewer than 50 employees. *Burwell v. Hobby Lobby Stores, Inc.*, 573 U.S. 682, 700 (2014) (citing The White House, *Health Reform for Small Businesses: The Affordable Care Act Increases Choice and Saving Money for Small Businesses*, at 1 (2010), <https://perma.cc/LHF7-7NZ3>).

integrated auxiliaries, and conventions or associations of churches,” as well as “the exclusively religious activities of any religious order,” from the Mandate. 78 Fed. Reg. at 39,874; *see* 26 U.S.C. § 6033(a)(3)(A)(i), (iii). The agencies also adopted a regulatory mechanism for compliance with the Mandate—termed an “accommodation”—by which religious employers not covered by the exemption could offer the objected-to contraceptives on their health plans by executing a self-certification and delivering it to the organization’s insurer, the plan’s third-party administrator (TPA), or to HHS. 80 Fed. Reg. 41,318 (July 14, 2015).

B. The challenges to the Mandate and the resulting injunctions

Because the Mandate required that many employers choose between violating their sincere religious beliefs and paying debilitating fines, dozens of challenges were filed against it. Most of those lawsuits relied on the Religious Freedom Restoration Act (RFRA). 42 U.S.C. § 2000bb *et seq.* RFRA prohibits federal agencies from imposing substantial burdens on religion—they “shall not” do it—unless they demonstrate that the burden is required by a compelling government interest and there is no “less restrictive” means of achieving that interest. 42 U.S.C. § 2000bb-1; *Hobby Lobby*, 573 U.S. at 728; *Little Sisters*, 591 U.S. at 668. Those lawsuits resulted in dozens of injunctions from federal courts across the country, four of which were consolidated at the Supreme Court. *See Zubik v. Burwell*, 578 U.S. 403 (2016) (consolidating cases from the Third, Fifth, Tenth, and D.C. Circuits).²

The Supreme Court unanimously vacated the decisions of the Third, Fifth, Tenth, and D.C. Circuits, which had ruled in favor of the agencies. *Id.* at 410. It noted a “substantial” change in the government’s position at the Supreme Court and ordered that the parties should be “afforded an opportunity to arrive at an approach going forward” that would resolve the dispute. *Id.* at 408. The

² The various cases challenging the Mandate prior to *Zubik* are collected at *HHS Case Database*, The Becket Fund for Religious Liberty, <https://perma.cc/N8ZA-2MW9>.

Court thus ordered the government not to impose taxes or penalties on petitioners for failure to comply with the Mandate and remanded the cases. *Id.* at 409-10.

Beyond the *Zubik* order, other injunctions from courts across the country prohibited the government from enforcing the Mandate against all known religious objectors. *See, e.g.*, Dkt. 206-1 at 7-9 nn.3-5. That includes injunctions that have been entered in open-ended class or associational standing cases that allow new members to join.³ These injunctions continue to bind the agency Defendants to this day such that Defendants are forbidden from enforcing the underlying Mandate against known religious objectors.

C. Challenges to the Interim Final Rules

In 2017, after years of unsuccessful attempts to justify the Mandate in court, the federal Defendants changed course. In compliance with Congress's mandate that government "shall not" impose a substantial burden on religion, and in compliance with injunctions forbidding enforcement against religious and moral objectors, *see, e.g., Zubik*, 578 U.S. at 1561, the federal Defendants issued two Interim Final Rules providing that the Mandate will not be enforced against employers with religious or moral objections. 82 Fed. Reg. 47,792 (Oct. 13, 2017) (Fourth IFR); 82 Fed. Reg. 47,838 (Oct. 13, 2017) (Fifth IFR).⁴ The IFRs otherwise left the Mandate in place as to all employers previously covered. The IFRs also left in place the accommodation. 45 C.F.R. § 147.131.

³ *See, e.g., Reaching Souls Int'l, Inc. v. Azar*, No. 5:13-cv-1092, 2018 WL 1352186, at *2 (W.D. Okla. Mar. 15, 2018) (granting permanent injunction to "employers participating in the GuideStone Plan"); Order, *Catholic Benefits Ass'n LCA v. Hargan*, No. 5:14-cv-240 (W.D. Okla. Mar. 7, 2018), Dkt. 184 (granting permanent injunction of Mandate to current and future nonprofit members of Catholic Benefits Association); Order, *Christian Emps. All. v. Azar*, No. 3:16-cv-309 (D.N.D. May 15, 2019), Dkt. 53 (granting permanent injunction to current and future members of Christian Employers Alliance).

⁴ Many of the arguments presented here are relevant to both the religious and moral exemption, but the Little Sisters address only the religious exemption. References to "IFR" or "Final Rule" in the singular are to that rule. The Little Sisters would only need to rely on the moral objector rule if the States argued, or the Court found, that the moral rule survives but the religious rule does not.

The IFRs were immediately challenged in this lawsuit, brought by the Commonwealth of Pennsylvania, and in others around the country. This Court entered a nationwide injunction preventing the implementation of the Fourth and Fifth IFRs on December 15, 2017, holding that the IFRs were invalid under the Administrative Procedure Act’s procedural and substantive provisions. Dkt. 60.

D. Ongoing proceedings

The agencies received comments and reviewed them. They then finalized the religious exemption in a final rule that took effect on January 14, 2019. 83 Fed. Reg. 57,536 (Nov. 15, 2018) (Final Rule). New Jersey joined this lawsuit in an amended complaint on December 14, 2018, and both States moved for a preliminary injunction of the Final Rule. This Court granted a preliminary nationwide injunction against the Final Rule on January 14, 2019, before the rules took effect. Dkt. 135. The agencies and the Little Sisters appealed that injunction to the Third Circuit, where those appeals were consolidated with the appeals of the injunction against the IFRs. The Third Circuit affirmed this Court’s injunctions.

E. The Supreme Court’s decision

The agencies and the Little Sisters appealed to the Supreme Court, which reversed by a vote of 7-2. The Court held that the Affordable Care Act “grants sweeping authority to HRSA” to issue guidelines and leaves HRSA with “unchecked” discretion “to identify and create exemptions from its own Guidelines.” *Little Sisters*, 591 U.S. at 676. In recognizing Congress’s “capacious grant of authority,” the Court noted that “no party has pressed a constitutional challenge to the breadth of the delegation” in the Mandate, and it upheld the Final Rule under the text of the statute. *Id.* at 676, 679. The Court also reasoned that a ruling striking down the Final Rule under the ACA would require the conclusion that the agencies also lacked authority to issue the initial church exemption and the “accommodation,” *Id.* at 677 n.7, and that “it would be passing strange for this Court to direct the Departments to make such an accommodation if it thought the ACA did not authorize

one.” *Id.* Considering whether the Final Rule would harm women, the Court held that “it is Congress, not the Departments, that has failed to provide the protection for contraceptive coverage.” *Id.* at 679.

The Court also considered the Third Circuit’s holding that RFRA did not give the agencies leeway to issue the Final Rule. The Court reiterated its prior holdings that government agencies “must accept the sincerely held complicity-based objections of religious entities,” and found that because its “decision[] all but instructed” the agencies to consider RFRA, “[i]t is hard to see how” the agencies could have complied with the Supreme Court’s holding without “overtly” considering religious objectors’ rights under RFRA. *Id.* at 681-82. Indeed, the Court explained, if the agencies had not applied RFRA, “they would certainly be susceptible to claims that the rules were arbitrary and capricious.” *Id.* at 682.

The Court also held that the rules were procedurally valid because the IFR “explained its position in fulsome detail and ‘provide[d] the public with an opportunity to comment,’” and because the Final Rules “explain[ed] that the rules were ‘necessary to protect sincerely held’ moral and religious objections.” *Id.* at 684, 686.

F. Proceedings in this Court

On August 20, 2020, the Third Circuit vacated this Court’s injunction and remanded for further proceedings. Dkt. 249.

On remand, the parties filed dispositive motions. While those motions were pending, the federal Defendants requested a stay to allow the Biden Administration to “evaluate the issues presented by this case.” Dkt. 269. The Court granted the stay on March 8, 2021, over the objection of the States and the Little Sisters. Dkts. 269, 271. The federal government requested and was granted further stays on April 30, 2021 and July 30, 2021, both of which were opposed by the Little Sisters, but not the States. Dkts. 274-75 & 280-81. On February 2, 2023—nearly two years after first requesting a stay—the agencies published a Notice of Proposed Rulemaking (NPRM)

that proposed to “maintain the religious exemption from the November 2018 Religious Exemption final rules.” Notice of Proposed Rulemaking, “Coverage of Certain Preventive Services Under the Affordable Care Act,” 88 Fed. Reg. 7236 (Feb. 2, 2023) . The proposed rule would have rescinded the moral exemption and established a new individual contraceptive arrangement (ICA), under which women employed by objecting entities could obtain contraception directly from a provider that offered it, independently from the woman’s health plan. *See id.* at 7252-7254. The comment period for the NPRM closed on April 3, 2023.

While the agencies considered comments on the NPRM, this Court denied the pending summary judgment motions without prejudice and continued the stay of the case in January 2024. Dkt. 311. On December 30, 2024, the agencies withdrew the NPRM. The Little Sisters now renew their motion for summary judgment in accordance with this Court’s orders. Dkts. 335, 337, 340.

ARGUMENT

I. The States lack Article III standing.

A. The States have no Article III injury.

In more than eight years of litigation, the States have never identified anyone who is, or would be, harmed by the Rules, even after this Court acknowledged this gap in their case. *See Pennsylvania v. Trump*, 351 F. Supp. 3d 791, 807 (E.D. Pa. 2019) (“Defendants point out that the States have not yet identified a woman resident who has lost contraceptive coverage due to the Final Rules”). Instead, the States have sat on their heels for the last four years, content to let the Rules stay in effect while the agencies considered new rules. At summary judgment, the States’ continued failure to establish any harm is dispositive.

Standing is “an indispensable part of the plaintiff’s case” on which it always “bears the burden of proof.” *Penn. Prison Soc’y v. Cortés*, 508 F.3d 156, 161 (3d Cir. 2007). As a case proceeds to summary judgment, “the manner and degree of evidence required” for the plaintiff to demonstrate standing rises. *Id.* At the preliminary injunction phase, the States only needed to show “more than

a mere possibility” of injury. *Pennsylvania*, 351 F. Supp. 3d at 805. “At summary judgment,” however, “a plaintiff ‘can no longer rest on ... mere allegations, but must set forth by affidavit or other evidence specific facts’ establishing”: (1) an injury; (2) traceable to the challenged action; (3) that is redressable by a decision from the court. *Greenberg v. Lehocky*, 81 F.4th 376, 384 (3d Cir. 2023) (quoting *Clapper v. Amnesty Int’l USA*, 568 U.S. 398, 412 (2013)); see *Freeman v. Corzine*, 629 F.3d 146, 153 (3d Cir. 2010) (plaintiff moving for summary judgment has burden to provide evidence “demonstrating that these requirements have been met”). The States have failed to offer any “affidavit or other evidence” demonstrating that any entity has declined contraceptive coverage due to the Final Rule being in effect.⁵

Nor can the States continue to rely on the expectation of future injury. While this Court previously excused the States’ omissions by saying “the States need not sit idly by and wait for fiscal harm to befall them,” the Final Rule granting religious exemptions has now been in effect in the States for over four years. *Pennsylvania*, 351 F. Supp. 3d at 803, 807 (injunction issued same day Final Rule was “scheduled to take effect”). Back then, the States told this Court that “the axe ... [was] about to fall on thousands,” *id.* at 828, but they make no effort to now to show their prediction correct even as to one.

Little Sisters further constricts any plausible claim of injury by holding that an exemption is permissible for sincere religious objectors to the “self-certification” system. See 591 U.S. at 681 (agencies had to “accept the sincerely held complicity-based objections of religious entities” and could exempt them); see also *id.* at 708 (Kagan, J., concurring in the judgment) (suggesting record explained “exempt[ing] the Little Sisters and other still-objecting groups from the mandate” since

⁵ The States rely on pre-enactment agency estimates (while critiquing them as understated), Dkt. 252-1 at 30, but they fail to identify any employer considered in those estimates not protected by a current court injunction. See 83 Fed. Reg. at 57,578 (Final Rule does not change status quo for entities that “have received permanent injunctions” in litigation).

the accommodation did not “‘assuage[]’ their ‘sincere religious objections’”). Thus, for most of the States’ claims, they would need to find an alleged harm traceable to employers *outside* those categories who have sought and received exemptions, and that *those* exemptions in turn have led to citizens of the States losing contraceptive coverage. Without that showing—which has not even been attempted—the States assert only a “general legal ... or policy objection to” the Final Rule that cannot support standing. *FDA v. All. for Hippocratic Med.*, 602 U.S. 367, 381 (2024) (Plaintiffs “may not sue based only on an ‘asserted right to have the government act in accordance with law’”).

B. The States cannot show redressability.

The States have not shown that their alleged injury can be cured by vacating the Final Rules. *Little Sisters*, 591 U.S. at 686-87. Three obstacles preclude this Court from redressing the claimed harm. First, the States have challenged the Final Rules but not the underlying HRSA guidelines (which separately provide an exemption). And second, regardless of the outcome of this case, the federal government is bound by dozens of other court orders precluding it from enforcing the Mandate against known objectors. Third, as set forth *infra* Parts II, III, and IV, the Constitution prohibits enforcement of the Mandate.

HRSA Guidelines. As the Supreme Court explained, the “contraceptive mandate” was “not required by (or even mentioned in) the ACA provision” on which it relies, but derives from a two-step agency process. *Id.* at 663. First, HRSA “develop[s] its Preventive Care Guidelines” with input from “recommendations” from outside volunteers and posts those guidelines on a website. *Id.* at 665; *see Hobby Lobby*, 573 U.S. at 697. Second, the agencies together “promulgate[] ... final rule[s]” that may modify the terms of any mandate under Section 300gg-13. *Little Sisters*, 591 U.S. at 665-67. The Guidelines and implementing regulations thus exist as two separate and independent administrative concepts.

Here, if the Court invalidates the Final Rules, religious objectors would theoretically be bound

to obey the HRSA guidelines. But those HRSA Guidelines separately address contraceptive coverage for religious objectors. J.A. 3474-75. And the States have not challenged the underlying HRSA Guidelines at all. As the Supreme Court acknowledged, the Guidelines have not been treated as coextensive with the implementing rules, and one may limit the other's effect. *See Little Sisters*, 591 U.S. at 666 (explaining that a 2012 final rule “temporarily prevented the Guidelines from applying to certain religious nonprofits”). HRSA Guidelines do not provide for “[c]ontraceptive methods and counseling” as a required service for religious objectors. To the contrary, the “HRSA-supported” Guidelines currently defer to the religious and moral exemptions in the Final Rules. Dkt. 341-2 at 7. Indeed, earlier versions of the Guidelines themselves excluded coverage for religious exemptions. J.A. 3474 (“These Guidelines ***do not provide for or support*** the requirement of coverage or payments for contraceptive services with respect to ... an objecting organization[.]”) (emphasis added); *see also Little Sisters*, 591 U.S. at 676-77 (affirming HRSA's authority to do so).

It is no idle formality to distinguish a challenge to the Final Rule from a challenge to the HRSA Guidelines. The States' briefing challenging the Final Rule focuses in large part on alleged APA deficiencies not phrased to apply to the Guidelines. *E.g.*, Dkt. 341-1 (“Mem.”) at 23-42. The States have not contended, for example, that HRSA must explain its Guidelines or must itself calculate the regulatory impact of its Guidelines if fully imposed as a mandate. Such arguments would have to be tailored to HRSA's “virtually unbridled discretion.” *Little Sisters*, 591 U.S. at 676. Thus, even if the States could prove that the Final Rules violate the APA, religious objectors would remain protected by HRSA's decision not to support application of the Guidelines to religious objectors. The States' claim is thus not redressable.

Injunctions. Likewise, the injunctions that pose obstacles to the States' showing of injury also make redress for the States' purported injuries even more remote. Religious objectors have obtained dozens of permanent injunctions against the Mandate. Dkt. 206-1 at 7-8 nn. 3-5

(collecting cases). The States need to demonstrate that an order from this Court vacating the Final Rules (but not vacating the injunctions) will somehow solve the States’ problems. They have failed to do so, or to even try.

II. The Mandate itself violates the nondelegation doctrine.

In *Little Sisters*, the Supreme Court also introduced a separate constitutional defense to the States’ claims, which also directly undercuts the States’ standing: the nondelegation doctrine. *Little Sisters*, 591 U.S. at 676. HRSA’s unchecked discretion forecloses the States’ claims, because neither this Court nor any other can give them the redress they seek, which is enforcement of the underlying Mandate.

The nondelegation doctrine bars Congress from delegating policymaking authority to agencies without “an intelligible principle to guide the delegatee’s use of discretion.” *Gundy v. United States*, 588 U.S. 128, 135 (2019) (plurality). Where “Congress ha[s] failed to articulate any policy or standard that would serve to confine” discretion, the delegating law is properly struck as violating separation of powers. *Mistretta v. United States*, 488 U.S. 361, 373 n.7 (1989); *see, e.g., Panama Refin. Co. v. Ryan*, 293 U.S. 388, 430 (1935) (striking down law that “declared no policy” and “established no standard” to guide the agency in delegated task). Such a doctrine is necessary to “protect the separation of powers and ensure that any new laws governing the lives of Americans are subject to the robust democratic processes the Constitution demands.” *Nat’l Fed’n of Indep. Bus. v. Dep’t of Lab.*, 595 U.S. 109, 124 (2022) (Gorsuch, J., concurring).

Here, the Supreme Court suggested that Section 300gg-13(a)(4)—the Mandate-enabling provision of the ACA—violates the non-delegation doctrine because “HRSA has virtually unbridled discretion to decide what counts as preventive care and screenings.” *Little Sisters*, 591 U.S. at 676. As a textual matter, the Court noted the ACA doesn’t provide “any criteria or standards to guide HRSA’s selections” despite the Act’s descriptive standards for other preventative care coverage “elsewhere in the same section of the ACA.” *Id.* (citing Section 300gg-13(a)(3))

(requiring “evidence-informed preventive care and screenings”) and Section 300gg-13(a)(1) (requiring “evidence-based items or services”). Congress was “completely silent” as to “any criteria or standards” and did not even provide an “illustrative” list to guide HRSA’s determinations. *Id.* Considering the ACA’s “capacious grant of authority” to HRSA, the Court emphasized that, “[the ACA] does not, as Congress has done in other contexts, require that HRSA consult with or refrain from consulting with any party in the formulation of the Guidelines.” *Id.*

The Court’s reasoning does the analytical work here: HRSA’s “unbridled discretion” under the ACA violates the intelligible principle standard. *See FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 536-37 (2009) (Kennedy, J., concurring in part) (explaining that “unbridled discretion” contravenes the “intelligible principle” rule protecting “separation of powers” (internal quotation marks omitted)). With no “policy or a standard” pronounced, Section 300gg-13(a)(4) delegates only power, not a principle, therefore violating the nondelegation doctrine. *Panama Refin.*, 293 U.S. at 416, 430. Section 300gg-13(a)(4) is thus void and cannot support any mandate.⁶

Further, the Little Sisters have repeatedly pressed the point that the States’ purported injury is only redressable if the Mandate would be enforceable against parties the Rules exempt. *See* Dkt. 206-1 at 11. And because *no* version of the Mandate would be enforceable if its enabling act is void as unconstitutional, the nondelegation question introduced by the Court is unavoidable.

Because the Supreme Court has both indicated that it would be proper for the parties to challenge “the breadth of the delegation” in this proceeding and suggested the delegation transgressed constitutional limits, this Court should reach the question of whether the Mandate

⁶ A majority of the Justices have said that they would reconsider the intelligible principle test. *See, e.g., Gundy*, 588 U.S. at 148-49 (Alito, J., concurring in judgment). Some Justices have suggested that a proper delegation means “assign[ing] to the executive only the responsibility to make factual findings” after Congress has “ma[d]e the policy judgments.” *Gundy*, 588 U.S. at 166 (Gorsuch, J., dissenting, joined by Roberts, C.J., and Thomas, J.); *see Paul v. United States*, 140 S. Ct. 342, 342 (2019) (statement of Kavanaugh, J.) (noting Justice Gorsuch’s view “may warrant further consideration in future cases”).

violates the nondelegation doctrine and properly find the States lack standing to challenge an exemption to a regulation based in a void law. *Little Sisters*, 591 U.S. at 679.

III. HRSA did not have authority to issue the Mandate under the Appointments Clause.

As with the nondelegation doctrine, Supreme Court precedent on the Appointments Clause also calls into question the validity of the Mandate’s enabling law—and in turn, whether the States’ purported injury can be redressed here. Under *Lucia v. SEC*, 585 U.S. 237, 237 (2018), the HRSA Administrator has been an “Officer[] of the United States” under the Appointments Clause since (at least) the passage of Section 300gg-13. U.S. Const. art. II, § 2 cl. 2. And because Congress has not specified “by law” that the role is exempt from presidential nomination and Senate confirmation, U.S. Const. art. II, § 2 cl. 2, all post-ACA appointments of the HRSA Administrator have violated the Appointments Clause, which requires full confirmation in the absence of contrary law. Therefore, the Administrators’ prior designations of preventive services—without which there can be no Mandate—have been *ultra vires*. Unwinding an exemption to an unenforceable regulation can redress no injury.

The Appointments Clause gives the President authority to “nominate, and by and with the Advice and Consent of the Senate, ... appoint ... Officers of the United States, whose Appointments are not herein otherwise provided for, and which shall be established by Law[.]” *Id.* The Clause provides only one exception to the Senate’s gatekeeping role as to every “officer”—that the House and Senate together “may by Law vest the Appointment of such inferior Officers, as they think proper, in the President alone, in the Courts of Law, or in the Heads of Departments.” *Id.*; see *Edmond v. United States*, 520 U.S. 651, 660 (1997) (Senate confirmation remains “default manner of appointment” unless Congress alters status quo). The Appointments Clause is “among the significant structural safeguards” limiting the Executive’s unilateral authority to fill significant roles. *Edmond*, 520 U.S. at 659-60.

Since this lawsuit was filed, the Supreme Court has made an important ruling on the distinction between “officers” and “non-officer employees” within the federal bureaucracy—one which, in combination with *Little Sisters*, removes any ambiguity that the HRSA Administrator is an officer. *Lucia*, 585 U.S. at 245. In *Lucia*, the Court provided “two guideposts” to “distinguish officers from employees.” *Lofstad v. Raimondo*, 117 F.4th 493, 498 (3d Cir. 2024). First, officers hold “a continuing office established by law.” *Lucia*, 585 U.S. at 247. Second, officers “exercise significant discretion,” *id.*, and “[h]aving significant duties and discretion” amounts to such authority. *Lofstad*, 117 F.4th at 498. Importantly, the *Lucia* majority determined the administrative law judges of the Securities Exchange Commission exercise significant discretion even though their decisions cannot be final and binding until “the SEC declines review (and issues an order saying so).” *Lucia*, 585 U.S. at 249.

Here, the HRSA Administrator meets the first guidepost for officer status, because it holds a continuing office established by law, with ongoing statutory duties extending beyond the administration of Section 300gg-13. *See* 47 Fed. Reg. 38,409, 38,410 (Aug. 31, 1982) (establishing Administrator); *see also, e.g.*, 42 U.S.C. § 254e(i)-(k) (assigning a continuing responsibility to the Administrator); 42 U.S.C. § 300b-10(c)(2) (same). The Administrator position has existed for over forty years, and the “duties continue, though the person performing the duties be changed.” The Test for Determining “Officer” Status Under the Appointments Clause, 49 Op. O.L.C. ___, at *5 (Jan. 16, 2025) (quoting *United States v. Maurice*, 26 F. Cas. 1211, 1214 (C.C.D. Va. 1823) (No. 15,747) (Marshall, C.J.)).

As to the second guidepost, the HRSA Administrator exercises wide discretion, amounting to “significant authority.” *See Little Sisters*, 591 U.S. at 676 (characterizing the HRSA as enjoying “virtually unbridled discretion” and “sweeping authority”). Further, the HRSA Administrator exercises greater independent control over a significant policy issue—the list of preventive care items to be mandated—than did the Commission judges in *Lucia*. And as *Lucia* establishes,

whether the agencies retain some power to limit the scope of HRSA's mandate does not deprive HRSA of significant authority or officer status. 585 U.S. at 249-50.

So the HRSA Administrator (with his current duties) is an Officer of the United States—one who has never undergone Senate confirmation.⁷ That would not be an issue if, for example, Congress had “by law vest[ed] the Appointment” in the President or the Secretary of HHS, who then duly made the appointment. U.S. Const. art. II, § 2 cl. 2. But Congress has *never* vested the appointment of the HRSA Administrator in any body. Rather, while Congress has assigned all manner of duties to the Administrator—duties which make him an Officer of the United States—the Administrator was created by the Executive itself, *and the Executive alone*, in a 1982 regulation issued by the Secretary of HHS. 47 Fed. Reg. at 38,409; *cf.* 5 U.S.C. § 301 (permitting an executive department head to “prescribe regulations for the government of his department”). Unless and until Congress passes a law that vests the appointment elsewhere, the HRSA Administrator may only be appointed by Senate confirmation. *Edmond*, 520 U.S. at 660. Because no HRSA Administrator has been so appointed, the duties of that Administrator that give rise to officer status may not be lawfully exercised—and any Mandate relying on HRSA's authority may not be enforced.

IV. The Mandate is unconstitutional under the First Amendment as applied to religious objectors.

If the States prevail in rolling back the Rules, the underlying Mandate would be impermissible under the Free Exercise Clause and the church autonomy doctrine.

A. The Mandate violates the Free Exercise Clause.

The Mandate cannot be applied to the Little Sisters, or other religious objectors, because doing

⁷ For example, Mary Wakefield served as Administrator between 2009 and 2015, when the Mandate and alternative method of compliance were first established, and was appointed by President Obama without Senate confirmation. *See President Obama Selects Top Rural Health Advocate to Oversee Key HHS Agency*, The White House Office of the Press Secretary (Feb. 20, 2009), <https://perma.cc/B76X-Y44F>.

so would violate the Free Exercise Clause. Developments in the law since this Court’s initial consideration of the case have made this clear. An exemption for religious objectors is necessary because the Mandate is not neutral and generally applicable for at least two independent reasons.

First, the Mandate permits individualized exemptions. The Supreme Court made clear in *Fulton v. City of Philadelphia* that “[t]he creation of a formal mechanism for granting exceptions renders a policy not generally applicable, regardless whether any exceptions have been given, because it ‘invite[s]’ the government to decide which reasons for not complying with the policy are worthy of solicitude.” *Fulton v. City of Philadelphia*, 593 U.S. 522, 537 (2021). It is law of the case that “HRSA has virtually unbridled discretion to decide what counts as preventive care,” and “the same capacious grant of authority ... leaves [HRSA’s] discretion equally unchecked in other areas, including the ability to identify and create exemptions from its own Guidelines.” *Little Sisters*, 591 U.S. at 676. In violation of the *Fulton* principle, HRSA has been given unchecked discretion to make exemptions. The existence of such discretion alone—“regardless whether any exceptions have been given”—triggers strict scrutiny. *Fulton*, 593 U.S. at 537.

Second, the Mandate also permits categorical exemptions. As the en banc Ninth Circuit has explained, it is “bedrock” First Amendment law that “the government may not ‘treat ... comparable secular activity more favorably than religious exercise.’” *Fellowship of Christian Athletes v. San Jose Unified Sch. Dist. Bd. of Educ.*, 82 F.4th 664, 686 (9th Cir. 2023) (en banc) (quoting *Tandon v. Newsom*, 593 U.S. 61, 62 (2021)); see also *Fulton*, 593 U.S. at 534 (“A law also lacks general applicability if it prohibits religious conduct while permitting secular conduct that undermines the government’s asserted interests in a similar way.”). Here, HRSA has—and has used—discretion to create categorical exemptions at will. And the ACA itself exempts grandfathered health plans, not only from providing contraceptives, but from providing *any* of the required preventive services. See 42 U.S.C. § 18011 (exemption); 45 C.F.R. § 147.140 (rules for grandfathered plans). While Pennsylvania has argued they are transitory, fifteen years

after the enactment of the ACA, they still exist, and in 2021 a rule went into effect which made it easier to maintain grandfathered status. *See* 45 C.F.R. § 147.140; <https://perma.cc/G764-VC4K> (“[t]he final rules will allow ... more flexibility to make changes to certain types of cost-sharing requirements without causing a loss of grandfather status.”). The law permits a for-profit company to refuse to provide contraceptive coverage for secular reasons, without any requirement that they authorize an alternative coverage scheme. But it prohibits the Little Sisters from declining to provide such coverage for religious reasons, unless they comply with an alternative scheme that is also religiously prohibited. Under “bedrock” First Amendment law, the Mandate must face strict scrutiny.

B. The Mandate violates the church autonomy doctrine.

The Mandate also independently violates the church autonomy doctrine. “[T]he general principle of church autonomy” is rooted in both the Free Exercise Clause and the Establishment Clause, and guarantees “independence in matters of faith and doctrine and in closely linked matters of internal government.” *Our Lady*, 591 U.S. at 747. That protection means, among other things, that government cannot make “explicit and deliberate distinctions between different religious organizations.” *Larson v. Valente*, 456 U.S. 228, 246 n.23 (1982) (striking down laws that treated differently “well-established churches” and “churches which are new and lacking in a constituency”). Indeed, any government action that “penetrates deeply into the internal affairs” of a religious body is prohibited by the Constitution. *Id.* at 253 n.29, 255. That principle ends this case.

Under the Mandate, some religious organizations get exemptions (primarily churches and their “integrated auxiliaries”), and some do not. That rule exempts religious orders which engage in what the government deems “exclusively religious” activities. *See* 78 Fed. Reg. at 39,874 (limiting exemption to the “exclusively religious activities of any religious order”). But it does not exempt religious orders that, because of their faith, engage in activities the government deems not

“exclusively religious,” such as serving the elderly poor.⁸

By preferring churches to other types of religious orders and organizations, the Mandate inappropriately interferes in protected “matters of internal government.” *Our Lady*, 591 U.S. at 747. These protected matters of internal government include the Sisters’ decision to maintain their independence as a religious order. Thus, in its original form, the Mandate places pressure on objecting religious organizations like the Little Sisters to either reorganize under the auspices of a church entity, or to abandon their beliefs altogether to avoid the Mandate’s fines. That pressure is impermissible.

The Mandate also discriminates among religious institutions “expressly based on the degree of religiosity of the institution and the extent to which that religiosity affects its operations.” *Colo. Christian Univ. v. Weaver*, 534 F.3d 1245, 1259 (10th Cir. 2008) (applying *Larson* to invalidate distinction between “sectarian” and “pervasively sectarian” organizations). Indeed, the pervasiveness or intensity of religious belief—as (allegedly) manifested in an organization’s hiring practices—was the agencies’ asserted basis for distinguishing between different religious organizations. 78 Fed. Reg. at 39,874 (churches “are more likely than other employers to employ people of the same faith who share the same objection”). Again, this kind of discrimination is impermissible.

Under the church autonomy doctrine, the government cannot second-guess religious judgments made by religious institutions, for “it is no business of [the government] to say that what is a religious practice or activity for one group is not religion under the protection of the First Amendment.” *Fowler v. Rhode Island*, 345 U.S. 67, 70 (1953). Again, the underlying Mandate does exactly that, granting certain churches and religious orders an exemption, while denying

⁸ The Supreme Court granted certiorari and heard argument this Term on this very issue. See *Catholic Charities Bureau, Inc. v. Wis. Lab. & Indus. Rev. Comm’n*, 3 N.W.3d 666 (Wis. 2024), *cert. granted*, 145 S. Ct. 1000 (argued March 31, 2025) (No. 24-154).

exemptions to others. Thus, if this Court again vacates the Final Rule, it will require the government to enforce an underlying regulation that is unconstitutional as applied to the Little Sisters. This Court should refuse to do so.

V. Under *Little Sisters*, the Final Rule does not violate the APA.

In holding that the Final Rule is permitted by the Affordable Care Act and that it was issued without “procedural defects,” the Supreme Court addressed many of the arguments upon which the States now rely. *Little Sisters*, 591 U.S. at 687. The States ask this Court to all but ignore the Supreme Court’s ruling in their attempt to argue that the Final Rule is arbitrary and capricious as applied to the very religious objectors the Supreme Court said it had “all but instructed” the agencies to consider. A fair application of *Little Sisters* forecloses the States’ claims.

A. The Final Rule is permitted by RFRA.

In *Little Sisters*, the Court reversed the Third Circuit’s holding that RFRA did not “authorize or require the Final Rules,” and that courts “owe the Agencies no deference when reviewing determinations based upon RFRA.” *Pennsylvania v. President*, 930 F.3d 543, 569, 572 (3d Cir. 2019), *rev’d and remanded sub nom. Little Sisters of the Poor Saints Peter & Paul Home v. Pennsylvania*, 591 U.S. 657 (2020). In holding that the agencies were authorized to consider RFRA, the Supreme Court noted “[i]t is hard to see how the Departments could promulgate rules consistent with these decisions if they did not overtly consider these entities’ rights under RFRA.” *Little Sisters*, 591 U.S. at 681-82.⁹ Under *Little Sisters*, then, it is permissible for the agencies to “simply reach[] a different conclusion on whether the accommodation satisfied RFRA.” *Id.* at 682 n.12.

The States ask this Court to reconsider that holding under the guise of an arbitrary and

⁹ After years of consideration, the Biden Administration seemed to have heeded the Supreme Court’s warning. The 2023 NPRM responding to the Final Rules and this lawsuit proposed to “maintain” the religious exemption in the final rules.

capricious analysis. The States must admit that the religious exemption was permitted by the ACA. Mem. 11-12. And they admit that the agencies properly “look[ed] to potential conflicts with RFRA to inform” the Final Rule. Mem. 29. In order to prevail, then, the States must necessarily argue that after properly considering both RFRA and the burden of fines that the accommodation placed on sincere religious belief, the *only* rational option was to deny an exemption. That conclusion is incorrect and inconsistent with *Little Sisters*. The Supreme Court determined that it need not decide whether the Mandate violated RFRA to determine that the agencies *could* offer a religious exemption based on the agencies’ understanding of RFRA. It makes no sense, then, to say that the agencies are actually *forbidden* from offering that religious exemption based on the States’ (misguided) interpretation of RFRA. That is especially true where dozens of courts required the very outcome the agencies decided upon, *see* Dkt. 206-1 at 7-8 nn.3-4, and where the Biden Administration, faced with these injunctions on the one hand and lawsuits like this one on the other, concluded that maintaining the religious exemption was the best outcome.

The States’ argument that the Final Rule is inconsistent with RFRA defies not only *Little Sisters*, but the text of RFRA itself, and the practice of every administration to apply RFRA since its adoption. *See Little Sisters*, 591 U.S. at 681 (“we directed the parties on remand to ‘accommodate[e]’” religious objectors). RFRA says explicitly that it “applies to all Federal law.” 42 U.S.C. § 2000bb-3(a); *see also* 42 U.S.C. § 2000bb-2(1) (“the term ‘government’ includes a[n] ... agency ... of the United States”). RFRA “intrude[s] at every level of government, displacing laws”—and therefore the regulations—of “every [federal] agency.” *Mack v. Warden Loretto FCI*, 839 F.3d 286, 301 (3d Cir. 2016). Accordingly, the Office of Legal Counsel has advised agencies that they can accommodate persons who they have reason to believe will face a substantial burden on religious exercise. *See, e.g., Application of the Religious Freedom Restoration Act to the Award of a Grant Pursuant to the Juvenile Justice and Delinquency Prevention Act*, 31 Op. O.L.C. 162, 176-77 (2007); *cf. Charitable Choice Regulations Applicable*

to States Receiving Substance Abuse Prevention and Treatment Block Grants, 68 Fed. Reg. 56,430, 56,435 (Sept. 30, 2003). Agencies have thus modified federal regulations to lift burdens on religious exercise, including issuing rules for agency adjudication of RFRA disputes under President Clinton,¹⁰ charitable choice regulations under President Bush,¹¹ regulations governing religious accommodations in the armed forces under President Obama,¹² the current regulations under President Trump, and regulations interpreting the Affordable Care Act’s nondiscrimination provision under President Biden.¹³

So too here, the agencies were obligated to protect religious exercise under RFRA. Congress made the Establishment Clause—not judicial pronouncements—the outer limit on exemptions: “Granting ... exemptions, to the extent permissible under the Establishment Clause, shall not constitute a violation of this chapter.” 42 U.S.C. § 2000bb-4; *accord Real Alts., Inc. v. Sec’y Dep’t of Health & Human Servs.*, 867 F.3d 338, 352 (3d Cir. 2017) (“the Government has discretion to grant certain religious accommodations subject to constitutional limitations.”). RFRA thereby expresses Congress’s intent that federal agencies are allowed to accommodate religious exercise. *See Little Sisters*, 591 U.S. at 682-83 (“looking to RFRA as a guide” is permissible in rulemaking). Indeed, more than permitted, the agencies were “instructed” to “develop and implement a solution” that complied with RFRA. *Id.* at 681.

¹⁰ See 14 C.F.R. § 1262.103(a)(4) (providing for NASA adjudication of RFRA disputes); 14 C.F.R. § 1262.101(b)(1)(iv) (providing for attorneys’ fees in such adjudications); 49 C.F.R. § 6.5 (providing for attorneys’ fees in Department of Transportation adjudications under RFRA).

¹¹ See, e.g., 42 C.F.R. § 54.3 (providing for nondiscrimination against religious organizations receiving certain funding); 42 C.F.R. § 54.5 (guaranteeing independence of religious organizations receiving certain funding).

¹² See Army Command Policy, *Accommodating religious practices*, Army Reg. 600-20 ch. 5-6 (Nov. 6, 2014) (prescribing religious accommodations under RFRA); see also 81 Fed. Reg. 91,494, 91,537 (Dec. 16, 2016) (citing RFRA to accommodate Native American eagle taking).

¹³ See 45 C.F.R. § 92.3(c) (acknowledging that federal conscience protections prevent some applications of nondiscrimination requirements).

The States argue that the Final Rule is inconsistent with RFRA because it does not require religious employers to claim a substantial burden before making use of the religious exemption. Mem. 20. But that misunderstands how civil rights laws work. Governments are permitted to lift burdens without individualized proof of each one. Thus, the EEOC can issue guidance on the enforcement of Title VII without needing each employee to claim discrimination. *See, e.g.*, EEOC, *EEOC Enforcement Guidance on National Origin Discrimination* (Nov. 18, 2016), <https://perma.cc/LSK6-H67X>. And Title IX applies to universities regardless of whether their students have asserted a burden. Here, the agencies have been told in thousands of comments and in dozens of court injunctions that the Mandate and the accommodation impose a substantial burden on sincere religious belief by imposing fines on employers who do not comply with the Mandate. The agencies recognize that the imposition of the penalties imposed by the Mandate for refusing to comply—“an enormous sum of money”—“clearly imposes a substantial burden.” *Hobby Lobby*, 573 U.S. at 726. And the Supreme Court explained in *Little Sisters* that it had “all but instructed” the agencies to consider RFRA, that they “must accept” the complicity-based objections from *Zubik*, and that they could not obey those decisions “if they did not overtly consider these entities’ rights under RFRA.” *Little Sisters*, 591 U.S. at 681-82. None of this would make any sense if, as the States suggest, no RFRA relief is even possible. Mem. 18. Rather, as the States acknowledge and as the Supreme Court plainly sees it, exempting employers who have sincere objections to the “[a]ccommodation” thus “target[s]” the “conflict” between the accommodation and RFRA. *Id.*

The States further complain that the exemption does not require notice that an employer is using an exemption because there is no way to determine the employer’s sincerity. Mem. 20. But they admit that “ERISA already mandates” notice to plan participants. Mem. 10; *see also* 29 C.F.R. § 2590.715-2715(b) (requiring notice of plan changes). ERISA also provides a check on an employer’s sincerity. The ACA’s provisions were incorporated by reference into Part 7 of ERISA.

29 U.S.C. § 1185d(a)(1). Under Part 7, a plan participant or beneficiary may bring a civil action “to recover benefits due to him under the terms of his plan, to enforce his rights under the terms of the plan, or to clarify his rights to future benefits under the terms of the plan.” 29 U.S.C. § 1132(a)(1)(B). An injured employee (if one ever comes forward) could thus challenge the sincerity of her employer in court, since the Final Rule requires that use of the exemption must be “based on [the employer’s] sincerely held religious beliefs.” 45 C.F.R. § 147.132(a)(2). Consistent with other civil rights law, having limited the exemption to those with sincere religious beliefs, the agencies are not required to police every instance in which the exemption is used, and the States’ arguments that the exemption is thereby arbitrary and capricious fail. *See, e.g.*, 34 C.F.R. § 106.12(b) (religious institutions “not required” to request exemption from Title IX in order to use exemption); *Maxon v. Fuller Theological Seminary*, 549 F. Supp. 3d 1116, 1125 (C.D. Cal. 2020) (granting motion to dismiss) (“intent of Congress, as evidenced by the plain language of [the statute]” was to require no “mandatory process” or self-certification).

The States’ argument is all the weaker for failing to address the agencies’ reasoning. They do not acknowledge, for instance, that the prior church exemption never asked exempt entities to engage in a self-certification process. 83 Fed. Reg. at 57,558. They do not acknowledge the agencies’ experience that such an approach neither “led to abuses [n]or to an inability to engage in enforcement.” *Id.* They do not explain how the prior church exemption (which they wish to retain) is not invalidated by the same arguments against the Final Rules (which they claim are illegal). And they never engage the agencies’ further reasons for continuing the no-certification approach for actually-exempt entities, including “additional public costs if those certifications or notices were to be reviewed or kept on file by the government.” *Id.* Without any evidence as to why the agencies were wrong to rely on their past experience with the identically-structured church exemption in predicting abuse, the States cannot reasonably claim that the exemption lacks a

“rational connection” to the RFRA concerns motivating the Final Rule. *Motor Vehicle Mfrs. Ass’n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983).

B. The Final Rule is required by RFRA.

In order to win their argument that the Final Rule is arbitrary and capricious as inconsistent with RFRA, the States must prevail on the argument that imposing the Mandate and accommodation on religious objectors like the Little Sisters does not violate RFRA. That argument was unpersuasive before *Little Sisters*, and the Court’s instructions in *Little Sisters* make it even more difficult for the States now. In *Little Sisters*, the Supreme Court reaffirmed its holding in *Hobby Lobby*, noting that “the contraceptive mandate violated RFRA as applied to entities with complicity-based objections.” *Little Sisters*, 591 U.S. at 681. The Court went on to explain that *Hobby Lobby* “made it abundantly clear that, under RFRA, the Departments must accept the sincerely held complicity-based objections of religious entities.” *Id.* The Court also reprised its instructions that courts “could not ‘tell the plaintiffs that their beliefs are flawed.’” *Id.*; *see also id.* at 708 (Kagan, J., concurring in the judgment) (“The measure thus failed to ‘assuage[]’ their ‘sincere religious objections.’”). To be sure, the Supreme Court did not apply strict scrutiny to determine that requiring the accommodation violates RFRA as applied to the Little Sisters, but it did reiterate the principles that doom the States’ arguments.

Substantial Burden. The substantial burden inquiry of RFRA is a simple two-part question: whether a religious belief is sincerely held and, if so, whether the government is “putting substantial pressure on an adherent” to act contrary to that belief. *Thomas v. Rev. Bd.*, 450 U.S. 707, 717-18 (1981); *see Sherbert v. Verner*, 374 U.S. 398, 404 (1963) (“the pressure upon [a Seventh-day Adventist] to forego [abstaining from Saturday work] is unmistakable”); *see also Hobby Lobby*, 573 U.S. at 695 n.3 (RFRA restored “*Sherbert* line of cases” and arguably “provide[s] even broader protection”).

The Little Sisters and other religious groups exercise religion by providing health insurance that complies with their religious beliefs. *See* J.A. 2290-91. Here, the accommodation depends on religious objectors contracting with their insurer or TPA to provide contraceptive coverage through their own plan infrastructure. Failure to comply with the Mandate, either outright or via the accommodation, would result in large fines under 26 U.S.C. § 4980D(b)(1) (\$100/day per person) and 26 U.S.C. § 4980H(c)(1) (\$2000 per employee, per year)—the same fines that constituted a substantial burden in *Hobby Lobby*. 573 U.S. at 691 (“If these consequences do not amount to a substantial burden, it is hard to see what would.”). For the Little Sisters, that penalty would be over \$2 million per year. J.A. 2294. The agencies themselves concede that forced compliance with the accommodation “constituted a substantial burden” on religious exercise. 82 Fed. Reg. at 47,806.

The States do not dispute that the Little Sisters and others have sincere religious objections to complying with the accommodation. But rather than address the burden’s magnitude—or perform any substantial burden analysis at all—the States refer only to *Real Alternatives* as holding that the accommodation does not impose a substantial burden. Mem. 18 (citing 867 F.3d at 356 n. 18).

Real Alternatives is inapplicable for at least three reasons. First, to the degree that the States use *Real Alternatives* to argue that religious objectors are mistaken about burden, the Supreme Court flatly rejected that argument. In *Fulton*, the city argued that no burden existed because the form the religious plaintiffs had to sign didn’t actually violate their religious beliefs: “[Philadelphia’s] view, certification reflects only that foster parents satisfy the statutory criteria, not that the agency endorses their relationships. But [Catholic Social Services] believes that certification is tantamount to endorsement.” *Fulton*, 593 U.S. at 532-33. And that ended the matter: “religious beliefs need not be acceptable, logical, consistent, or comprehensible to others in order to merit First Amendment protection.” *Id.* (quoting *Thomas*, 450 U.S. at 714).

Second, *Real Alternatives* does not render the agencies’ RFRA analysis arbitrary and capricious. Faced with court decisions around the country coming to different conclusions about

whether the accommodation imposes a substantial burden, the agencies cannot reasonably be accused of arbitrariness in their attempt to avoid a possible RFRA violation as well as an APA violation. *See Little Sisters*, 591 U.S. at 682 (“If the Departments did not look to RFRA’s requirements or discuss RFRA at all when formulating their solution, they would certainly be susceptible to claims that the rules were arbitrary and capricious for failing to consider an important aspect of the problem.”). Particularly where the analysis in *Real Alternatives* has been twice vacated by the Supreme Court, the agencies cannot be faulted for declining to follow it. *See Geneva Coll. v. Sec’y U.S. Dep’t of Health & Human Servs.*, 778 F.3d 422, 439 (3d Cir. 2015), *vacated sub nom.*, *Zubik*, 578 U.S. 403; *Pennsylvania v. President*, 930 F.3d at 573, *rev’d and remanded sub nom. Little Sisters*, 591 U.S. 657.

Third, *Real Alternatives* does not help the States on the merits. As an initial matter, it does not address the accommodation’s burden on religious employers. 867 F.3d at 354-55 (calling employee claim “a question of first impression” and “distinct from an employer’s RFRA claim objecting to the mandated provision” of coverage). By citing *Real Alternatives*, the States attempt to import the vacated decision in *Geneva College*, 778 F.3d at 439. But the majority in *Real Alternatives* specifically disclaimed treating *Geneva College* as precedential, 867 F.3d at 356 n.18 (“*Geneva* is no longer controlling”), and specifically distinguished the RFRA claim of the employees from that of an employer facing the accommodation. *Id.* at 362 (“There is a material difference between employers arranging or providing an insurance plan that includes contraception coverage” and an employee’s act of signing up for the plan).

Moreover, the vacated opinion in *Geneva College* was procured on incorrect facts, as the federal government later admitted. Specifically, in *Geneva College*, the agencies repeatedly told the Court that contraceptive coverage under the “accommodation” was *not* part of the religious organization’s health plan. *See, e.g., Br. for Appellants, Geneva Coll. v. Sebelius*, No. 14-1376, 2014 WL 2812346, at *1-2 (3d Cir. June 10, 2014), *vacated and remanded sub nom. Zubik*, 578

U.S. 403) (“[i]n all cases” contraceptive coverage “is provided separately from [the religious employer’s] health coverage”). The *Geneva College* panel accepted these representations as true and relied on them in making its substantial burden holding. *See Geneva Coll.*, 778 F.3d at 439 (coverage is “separate and apart from” religious employer’s plan).

Before the Supreme Court in *Zubik*, however, the agencies admitted that the accommodation “coverage” actually *is* “part of the same ‘plan’ as the coverage provided by the employer.” Br. for Resp’ts at 38, *Zubik*, 578 U.S. 403, <https://perma.cc/MAR4-D59H>; *see also* Tr. of Oral Arg. at 60-61, *Zubik*, 578 U.S. 403, <https://perma.cc/EZ6G-KDVH> (admitting it is “a fair understanding of the case” that all services are “in the one insurance package”). *Real Alternatives* did not have an opportunity to take account of these facts, because it did not address the religious exercise at issue here.

Religious objectors like the Little Sisters are required to execute Form 700, obligating their insurer to provide contraceptives to their employees through their plan infrastructure. 45 C.F.R. § 147.131(d). Or they must alternately inform HHS in writing not only of their religious objection, but also of the “name and type” of their plan, along with contact information for the health insurance issuers, and must keep HHS updated with changes to that information. 45 C.F.R. § 147.131(d)(1)(ii). In the case of religious entities with a self-insured plan—that is, a plan where the financial risk of claims is not borne by an insurance company—the notification via Form 700 or directly to HHS serves to “designate the relevant [TPA] as plan administrator,” a role a TPA does not normally have, and that requires legal authority from the employer, such that the notification becomes “an instrument under which the plan is operated.” 79 Fed. Reg. 51,092, 51,095 (Aug. 27, 2014). That is not simply “opt[ing] out.” Mem. 5. It is using legal authority to authorize and obligate a TPA to use the religious organization’s plan to provide coverage.

Regardless of the plan type, the regulations themselves announced that they relied on the employer’s “coverage administration infrastructure” to achieve the Mandate’s coverage goal. 80

Fed. Reg. at 41,328. The third-party administrator would contact all plan participants, identify them by “payroll location,” and perform “[o]ngoing, nightly feeds” of information. J.A. at 1220-22 (Guidestone Declaration), *Zubik*, 578 U.S. 403, <https://perma.cc/YSV2-XUNC>; *see also* 80 Fed. Reg. at 41,328-29 (acknowledging the plan information is used to “verify the identity” of beneficiaries and “provide formatted claims data for government reimbursement”).

Religious employers making use of the accommodation are thus forced to maintain a health plan that provides the very coverage the employer finds religiously objectionable. *See* 78 Fed. Reg. at 39,876 (“plan participants and beneficiaries (and their health care providers) do not have to have two separate health insurance policies (that is, the group health insurance policy and the individual contraceptive coverage policy)”). Thus, “the coverage provided by the TPA is, as a formal ERISA matter, part of the same ‘plan’ as the coverage provided by the employer.” Br. for Resp’ts at 38, *Zubik*, 578 U.S. 403, <https://perma.cc/MAR4-D59H>.

That is why Solicitor General Verrilli conceded that contraceptive coverage must be “part of the same ‘plan’ as the coverage provided by the employer,” Br. for Resp’ts at 38, *Zubik*, 578 U.S. 403, <https://perma.cc/MAR4-D59H>; Tr. of Oral Arg. at 60-61, *Zubik*, 578 U.S. 403, <https://perma.cc/EZ6G-KDVH> (Chief Justice Roberts: “You want the coverage for contraceptive services to be provided, I think as you -- as it said, seamlessly. You want it to be in the one insurance package. ... Is that a fair understanding of the case?”; Solicitor General Verrilli: “I think it is one fair understanding of the case.”). The Supreme Court itself recognized the government’s “substantial clarification and refinement” in its position, *Zubik*, 578 U.S. at 408, which is why it makes no sense for the States to rely on pre-*Zubik* analysis of the substantial burden from a case that was vacated by *Zubik*. *See* Mem. 21. That is particularly true now that the Supreme Court has reaffirmed that agencies “must accept the sincerely held complicity-based objections of religious entities.” *Little Sisters*, 591 U.S. at 681.

The States do not challenge the Little Sisters' sincerity and have not attempted to show that the Little Sisters are *factually* mistaken about the accommodation. And civil courts do not decide theological questions. *See, e.g., Thomas*, 450 U.S. at 715-16 ("it is not for us to say that the line [plaintiff] drew was an unreasonable one").

Finally, it would make no sense for the Supreme Court in *Little Sisters* to say that the agencies should have "overtly consider[ed] these entities' rights under RFRA" if it actually meant that these entities have no rights under RFRA because there is no burden. 591 U.S. at 682. To the contrary, the Court said that it had "left it to the Federal Government to develop and implement a solution," and that the agencies "must accept the sincerely held complicity-based objections of religious entities." *Id.* at 681. To be sure, the Court did not prescribe the exact outcome of RFRA's strict scrutiny analysis. But it is absurd to suggest that "must accept" actually means "must ignore." *Id.* Rather, the only way "these entities[]" could have any "rights under RFRA" to be considered at all is if there is a substantial burden. *Id.* at 682.

Strict Scrutiny. Under RFRA, Congress permitted agencies to impose substantial burdens on religion only where the federal government proves that imposing the burden on a particular person is the least restrictive means of advancing a compelling government interest. 42 U.S.C. § 2000bb-1. "Put another way, so long as the government can achieve its interests in a manner that does not burden religion, it must do so." *Fulton*, 593 U.S. at 541. Here, the government cannot carry that burden and, to its credit, has finally stopped trying. *See* 83 Fed. Reg. at 57,546-49 (explaining why the Mandate and accommodation violated RFRA and failed strict scrutiny).

Any interest in requiring employers to provide contraceptives cannot be "compelling" since small businesses, grandfathered plans, churches, and government-sponsored plans are exempt. These existing exemptions do "appreciable damage" to any alleged interest in universal seamless coverage, showing that it cannot be an interest "of the highest order." *Church of Lukumi Babalu Aye, Inc. v. City of Hialeah*, 508 U.S. 520, 546-47 (1993). For example, the Obama Administration

defended its decision to exempt grandfathered plans by explaining that affected women would have many other avenues to obtain coverage, including “through a family member’s employer, through an individual insurance policy purchased on an Exchange or directly from an insurer, or through Medicaid or another government program”—that is, non-seamless means. Br. for Resp’ts at 65, *Zubik*, 578 U.S. 403, <https://perma.cc/MAR4-D59H>. Similarly, the government argued that the grandfathering exemption—covering over 49 million people, *Hobby Lobby*, 573 U.S. at 700—did not undercut the government’s interests because “*most* women currently covered under grandfathered plans likely have (and will continue to have) *some* contraceptive coverage.” Br. for Resp’ts at 64, *Zubik*, 578 U.S. 403 (emphasis added), <https://perma.cc/MAR4-D59H>. These concessions are partly why the Supreme Court remanded *Zubik* and why the government was subject to numerous injunctions following *Zubik*.¹⁴

Even so, the States cannot seriously contend there is a compelling interest in prohibiting actions they themselves do not prohibit. Pennsylvania has no contraceptive mandate at all, J.A. 3412, and at least as of its entry in the case, the record reflects New Jersey’s mandate includes cost-sharing and a religious exemption broader than that in the federal Mandate. J.A. 3416. Indeed, the States’ positions in this litigation demonstrate that, even to them, the interest in removing the Final Rule is not compelling. The States were content to allow their fully briefed summary judgment motions to remain pending while the Final Rule remained in effect for years, and only now do they ask this Court to mitigate the harm they claim it causes. Their contentment to accede to the prior administration’s inaction shows that any interest in overturning the Final Rules can take a back seat to other political priorities. *See supra* Part I.

The States claim that the government did not sufficiently consider less restrictive means, Mem.

¹⁴ See Mark L. Rienzi, *Fool Me Twice: Zubik v. Burwell and the Perils of Judicial Faith in Government Claims*, 2016 Cato Sup. Ct. Rev. 123 (2015-2016) (detailing concessions leading to the *Zubik* remand).

22, but the government is already attempting to provide Title X-funded contraceptives for women whose employers conscientiously object to contraceptive coverage. 84 Fed. Reg. 7714, 7734 (Mar. 4, 2019). The States themselves attest to a range of state programs that provide contraceptives. J.A. 3438-48. The very existence of those programs proves that a plan run by nuns is not the least restrictive means of distributing contraceptives.

Finally, any third-party harm, to the extent that it exists, is not the result of the religious objector seeking to have contraceptives banned, but because the government has chosen to force third parties to distribute a product. The Little Sisters' beliefs about contraceptives are cost free; the alleged "cost" comes in only because the government initially chose the Little Sisters, rather than some other delivery method, to provide such coverage. Per *Hobby Lobby*, the burdens on third parties are properly considered under the compelling interest test, not as a separate exception to RFRA. 573 U.S. at 731-32. As described above, that interest is not compelling here.

C. The Final Rule contains a sufficient explanation of its findings.

The Supreme Court has already found that "[t]he final rules included a concise statement of their basis and purpose, explaining that the rules were 'necessary to protect sincerely held' moral and religious objections and summarizing the legal analysis supporting the exemptions." *Little Sisters*, 591 U.S. at 686. The Court also noted that the Final Rule contained a "lengthy analysis" regarding why the agencies changed their position on the accommodation. *Id.* at 673. That should be enough to dispose of the States' claim that the agencies do not offer a reasoned explanation for the exemption. *See, e.g., FDA v. Wages & White Lion Invs., L.L.C.*, 604 U.S. ---, 142 S. Ct. 898, 918 (2025) (when changing positions, "the agency does not need to show 'that the reasons for the new policy are *better* than the reasons for the old one.' Nor must it 'provide a more detailed justification than what would suffice for a new policy created on a blank slate.'" (internal citations omitted) (quoting *Fox Television*, 556 U.S. at 515)). Indeed, that the Final Rule offered a solution to problems presented by thousands of comments, dozens of injunctions, and a Supreme Court

order is reason enough for the change in policy for an exemption. *See Little Sisters*, 591 U.S. at 681-82, 682 n.12 (“[O]ur decisions all but instructed the Departments to consider RFRA going forward.” And the Final Rule “had to account for RFRA in response to comments that the rules would violate that statute.”).

Yet the States maintain that the agencies have not offered a sufficient explanation for the Final Rule, citing a higher standard because it “rests upon factual findings that contradict those which underlay” the agencies’ prior policies and because the prior policy “engendered serious reliance interests.” Mem. 23. The use of the higher standard is questionable because the States have been unable to show evidence of anyone with a reliance interest that is threatened, *see supra* Section I.A, and because the Final Rule does not “rest upon factual findings” contrary to prior agency regulations, but simply points out that the facts are not as certain as prior rules indicated, *see* 83 Fed. Reg. at 57,555 (highlighting “uncertainty and ambiguity” rather than “tak[ing] a position” on empirical questions). Under any standard, however, the agencies have hardly “ignore[d]” or “disregard[ed]” any facts or circumstances. *Fox Television*, 556 U.S. at 515. Their “lengthy analysis” has taken into account all of the concerns the States raise. *Little Sisters*, 591 U.S. at 673.

The “Accommodation” as an Opt-Out. The States continue to characterize the accommodation as simply “opt[ing] out” of contraceptive coverage. *See* Mem. 5. In the Fourth IFR and the Final Rule, the agencies explained why this is incorrect: “the existing accommodation with respect to self-insured plans requires contraceptive coverage as part of the same plan as the coverage provided by the employer, and operates in a way ‘seamless’ to those plans.” 82 Fed. Reg. at 47,809. The accommodation’s structure continued to require employers to provide plans with objectionable coverage, even if payments were segregated—meaning it failed to “accommodate” objectors’ theological concerns about complicity. “As a result, in significant respects, that previous accommodation process did not actually accommodate the objections of many entities, as many entities with religious objections have argued.” 83 Fed. Reg. at 57,544. This is the precise religious

objection that was at issue in *Zubik* and that *Little Sisters* explains the agencies were instructed to address. *Little Sisters*, 591 U.S. at 681-82 (“It is hard to see how the Departments could promulgate rules consistent with [*Hobby Lobby* and *Zubik*] if they did not overtly consider these entities’ rights under RFRA.”).

Burden Not Justified by Compelling Interest. The States object that the agencies have wrongly changed their position on the government’s interest at stake in the Mandate. Mem. 22. But the agencies rightly recognized that employers being made to choose between “significant penalties” and involvement with contraceptive coverage in a manner “inconsistent with their religious observance or practice” was the precise “substantial burden identified by the Supreme Court in *Hobby Lobby*.” 83 Fed. Reg. at 57,545-46. As such, the agencies had the burden to show a compelling interest served by enforcing the Mandate against religious objectors, and that doing so was the least restrictive means of serving the interest. They reasonably concluded that the link between the Mandate and contraceptive access and use was “not clear,” and that enforcing the Mandate as a means to those goals was not a compelling interest. *See* 83 Fed. Reg. at 57,556. The agencies also recognized that any interest in denying the exception to religious objectors specifically—RFRA’s “burden to the person” inquiry, 42 U.S.C. § 2000bb-1(b)—was further reduced by the fact that “many or most women potentially affected by the expanded exemptions. . . . may not be impacted by these rules at all” in light of other exceptions and permanent injunctions that prevented the Mandate’s application. 83 Fed. Reg. at 57,550. The agencies also provided legal analysis on why an interest in “seamlessness” would likely fail the Supreme Court’s standards for a compelling interest. 83 Fed. Reg. at 57,548 (detailing damage to that interest under current law). Further, the States’ own declarations undercut the idea that allowing a few more employers to access a religious exemption would threaten the interests served by the Mandate, given that those declarations tout the comprehensive effectiveness of a system that has always incorporated broader exemptions. *See, e.g.*, J.A. 3424 (“Since the ACA passed, no

patient has contacted me to ask for a different, cheaper method of contraception than the one I had prescribed[.]”); J.A. 3436 (“Post-ACA, the only concern has been what is best for the patient.”).

Empirical Questions. The States argue that the agencies reversed their conclusions on the benefits, safety, and efficacy of contraceptives. Mem. 23-29. But the agencies explicitly did “*not* take a position on the variety of empirical questions” the States accuse them of reversing. 83 Fed. Reg. at 57,555 (emphasis added). And they did not need to do so because the exemption did not rely on those empirical questions. The agencies simply pointed to evidence that “uncertainty and ambiguity exists,” which undermines the agencies’ prior denials of an exemption. *Id.* That ambiguity is consistent with the United States Preventive Services Task Force, which does not list contraceptives as a recommended preventive service (and never has). *See* U.S. Preventive Services Task Force, *Published Recommendations*, <https://perma.cc/RB5R-529J>.

Nor is it in any way improper—much less arbitrary and capricious—that the agency considered commenters’ views that some FDA-approved contraceptives constitute abortifacients. Mem. 23. When the agencies have been “directed” to accommodate religious beliefs, *Little Sisters*, 591 U.S. at 681, considering commenters’ views does not mean that the agencies used religious beliefs to “evaluat[e] the health effects of contraception,” Mem. 26.

Reliance Interests. The States are wrong to suggest that the agencies “fail[ed] to consider the reliance interests of the women who stood to lose contraceptive coverage.” Mem. 28. The agencies specifically considered the potential harms to third parties, including women who might lose contraceptive coverage through their employer. *See* 83 Fed. Reg. at 57,548-52. The agencies explained that there had not been a meaningful increase in contraceptive use under the Mandate, largely because of the wide availability of low-cost or free contraception through multiple publicly funded programs. *See* 83 Fed. Reg. at 57,548. Thus, only a relatively few women were relying on the Mandate to obtain contraceptives. Given the very low reliance rates, and the easy access to contraception through other means, the agencies reasonably concluded that the Rules would not

“have any of the drastic negative consequences on third parties or society that some opponents of these rules have suggested.” 83 Fed. Reg. at 57,552.

Reasonable Alternatives. The States contend that the agencies failed to consider any reasonable alternatives to the Final Rules that would have protected access to contraceptive coverage. Mem. 32. But agencies “need not consider every alternative proposed nor respond to every comment made. Rather, an agency must consider only ‘significant and viable’ and ‘obvious’ alternatives” and provide reasoned explanations for their ultimate decision. *Nat’l Shooting Sports Found., Inc. v. Jones*, 716 F.3d 200, 215 (D.C. Cir. 2013) (internal citations omitted). That’s exactly what the agencies did, as another court has already held. *See Massachusetts v. HHS*, 513 F. Supp. 3d 215, 225 (D. Mass. 2021).

First, the States assert that the agencies failed to consider limiting the scope of the expanded exemption to “employers with complicity-based objections” to the accommodation. Mem. 33-34. But the States do not point to “any evidence showing that” this suggestion “was a serious issue raised by any commenter.” *Nat’l Shooting Sports Found.*, 716 F.3d at 217. And for good reason: the agencies’ rules for religious employers already limit both the exemption and the accommodation to employers whose sincere religious beliefs are burdened by the Mandate. 83 Fed. Reg. at 57,543. It was entirely reasonable for the agencies to allow religious employers to select the option (exemption or accommodation) that best reflects their sincere religious beliefs. As the agencies pointed out, expanding the exemption while keeping the optional accommodation in place avoided the unfair line-drawing that led to so many constitutional challenges to the original, narrow exemption. 83 Fed. Reg. at 57,542; *see also Larson*, 456 U.S. at 244.

Second, the States suggest that the agencies could have simply expanded or adjusted the existing accommodations. Mem. 34. The agencies specifically considered similar suggestions and explained that this approach was not practical given that all available alternatives for expanding the accommodation would still “likely violate some entities’ religious objections,” 83 Fed. Reg. at

57,545-46, and thus “would not adequately address religious objections to compliance with the Mandate.” 83 Fed. Reg. at 57,544. Again, the agencies’ chosen course was preferable—even required—under RFRA.

Third, the States do not dispute that the agencies explained why the option of narrowing or eliminating the moral exemptions would not be appropriate. Mem. 35; *see also Massachusetts*, 513 F. Supp. 3d at 225 (rejecting Massachusetts’ identical argument). The States simply disagree with the analysis that the agencies provided. But disagreeing with an agency’s analysis, even if the analysis is “not without flaw,” does not mean that the agency failed to adequately justify its changed position. *Prometheus Radio Project v. FCC*, 373 F.3d 372, 424-25 (3d Cir. 2004) (upholding changed policy over objections that the agency’s reasoning ignored some aspects of the problem). And to the extent the Court concludes that the moral exemptions are insufficiently justified, they are easily severable. *See infra* Section V.E.

Fourth, the States insist that the agencies refused to consider creating a separate process for women employed by exempt entities to obtain contraceptive coverage—the Individual Contraceptive Arrangement, or ICA. Mem. 35-36. But the only source the States cite for the ICA idea is the “now-withdrawn 2023 Proposed Rule.” *Id.* (citing 88 Fed. Reg. at 7243). The agencies can hardly be faulted for failing to consider in 2018 a proposal which was not made until 2023.

To the extent that the States fault the agencies for not engaging with the general suggestion that women could gain access to contraceptives separately from their objecting religious employer’s health plan, the answer is simple. Mem.36 (citing general comments about alternative access made during litigation over the Mandate). The agencies *did* consider this possibility. While responding to comments about possible harms to third parties, the agencies explained that “the availability of contraceptive coverage from other possible sources ... detracts from the government’s interest to refuse to expand exemptions to the Mandate.” 83 Fed. Reg. at 57,548. In fact, the Mandate had not brought about any meaningful increase in contraceptive use, in large part

because contraceptives were already widely available “at low or no cost through publicly funded family planning centers and Medicaid,” as well as “through programs such as Title X.” *Id.* In other words, because many alternative sources for contraception already existed, the agencies reasonably concluded that they did not need to create yet another mechanism for obtaining contraception.

This also addresses the States’ contention that the agencies ignored their obligation not to create “unreasonable barriers” to contraceptive access under Section 1554 of the ACA (despite the voluntary dismissal of their Section 1554 claim). Mem. 37. The agencies acted reasonably considering (1) the existing injunctions requiring them to provide broader protections for religious objectors, (2) the wide availability of contraceptives generally, and (3) Title X programs available to provide contraceptives. Indeed, Congress itself chose not to mandate contraceptive coverage at all—leaving the matter entirely to HRSA’s discretion—and chose to allow grandfathered plans serving tens of millions of women to not cover preventive services. In light of these choices, it makes no sense to suggest that the ACA treats failure to extend a mandate to each and every potential employer as “creat[ing] an[] unreasonable barrier[]” or “imped[ing] timely access to health care.” 42 U.S.C. § 18114.

The Final Rule does not place unreasonable barriers on or impede any woman’s timely access to contraception because that ability “remains unfettered,” *California ex rel. Becerra v. Azar*, 950 F.3d 1067, 1093 (9th Cir. 2020) (en banc) (rejecting Section 1554 challenge to new Title X regulations), as the agencies explained. *See* 83 Fed. Reg. at 57,548. Indeed, to this day, the States still cannot identify one woman who cannot obtain coverage as a result of the Final Rules, nor even one who was unable to obtain coverage because of the many prior injunctions. In short, the Final Rule “does not improperly impose regulatory burdens on doctors and patients” and is therefore fully consistent with Section 1554 of the ACA. *See Becerra*, 950 F.3d at 1094.

“Ultimately, even if the Departments did not consider every conceivable alternative, such vigorous analysis is not required under the APA. Defendants fulfilled their obligation by properly

considering a number of reasonable alternatives and offering an explanation for why they were rejected.” *Massachusetts*, 513 F. Supp. 3d at 225.

Comments. The States are also wrong, as this Court and the Supreme Court have already held, that the agencies did not consider significant comments. Mem. 37-40. The States do not address the Supreme Court’s statement that the agencies “responded to post-promulgation comments, explaining their reasons for neither narrowing nor expanding the exemptions beyond what was provided for in the IFRs.” *Little Sisters*, 591 U.S. at 672-73. Additionally, this Court held in its second preliminary injunction opinion that the Final Rule met the “relatively low bar” for acknowledging comments and offering a response. Dkt. 136 at 26-27. Instead, the agencies claim that the bulk of the comments on the IFR were against an exemption. But they ignore the thousands of comments filed on prior versions of the accommodation and mandate asking for the solution provided here, as well as the litigation brought by dozens of religious objectors. The agencies should not have to review comments with blinders on that force them to ignore the knowledge gained from their prior rulemakings.

Regulatory Impact Analysis. The States take issue with the agencies’ assessment of the regulatory impact of the Final Rule. Mem. 40-43. But it is difficult to see how the arbitrariness of that specific part of the Rule would render all of the reasoning of the Final Rule arbitrary and capricious along with it. The Final Rule clearly explains that the impact analysis is “[s]olely for the purposes of” complying with Executive Order 12,866—an administrative requirement—not for determining whether to offer the exemption. 83 Fed. Reg. at 57,550. The agencies stated that there is “not reliable data available to accurately estimate the number of women who may lose contraceptive coverage” under the Final Rule. *Id.* A change in the estimate is therefore unlikely to change the analysis in the Final Rule. Indeed, though the agencies estimate that the Final Rule will cost “well below” the amount necessary to consider the Rule “economically significant,” the Office of Management and Budget (OMB) treated the Final Rule as significant anyway, triggering

the OMB review and impact analysis required for “economically significant” regulations. *Id.* at 57,550, 57,573. A change in the regulatory impact analysis thus cannot effect a change on the rest of the Final Rule.

In any case, the States are wrong about the impact analysis, where the agencies provide detailed explanation of their estimates. The States admit that the agencies estimate some employees to have dependents, Mem. 40, but confusingly claim without citation that those dependents did not factor into the agencies’ analysis, when they clearly did. *See* 83 Fed. Reg. at 57,576 & n.86.

Next, the States suggest that the agencies raised the number of possible employees affected between the interim final rule and the Final Rule without an explanation. Mem. 41. But that hardly supports the States’ argument that the agencies underestimate the impact on employees. The States object that the agencies estimated that some hospitals will continue using the accommodation rather than the exemption because hospitals informed the agencies that the accommodation satisfied their religious objections. Mem. 41-42. The States’ objection appears to be that the hospitals notified the agencies rather than submitting formal comments. 83 Fed. Reg. at 57,561. But the States ignore the agencies’ acknowledgement of comments from “similar nonprofit employers indicating that the accommodation satisfied their religious objections.” *Id.* The States appear to object to the fact that the employers did not commit to continuing use of the accommodation once the exemption was available. But they do not explain why an employer would remove coverage from their employees if it didn’t violate their belief or cost them any money to continue doing so. And the possibility that employers who do not have a sincere religious belief that requires using the exemption would be violating the Affordable Care Act and subjecting themselves to fines seems like it would be a sufficient barrier.

Finally, the States accuse the agencies of *reducing* the number of employees who will be affected by the Final Rules based on survey data that reflects whether employers provided contraceptive coverage before the ACA required it. But that survey data did not reflect the religious

beliefs of employers, only their practices. So *any* estimate about whether they would take advantage of the religious exemption is based on speculation. As the agencies noted in the Final Rule, survey results that do address religious beliefs find that “only 4% of Americans believe that using contraceptives is morally wrong.” 83 Fed. Reg. at 57,580.

These objections, rather than exposing the Final Rule as arbitrary and capricious, show the extent to which the agencies provided explanations that reflected detailed analysis. The States’ suggestions that the Final Rule will cause massive harm are undermined by their inability to show any of that harm even after the exemption has taken effect. *See supra* Section I.A. At bottom, though, by picking at minor points of the agencies’ “lengthy analysis,” *Little Sisters*, 591 U.S. at 673, the States hope to revisit the Supreme Court’s holding that the Final Rule is permissible, *even though* there may be employees who do not receive contraceptive coverage as a result.

D. The Final Rule is not overbroad.

In her *Little Sisters* concurrence, Justice Kagan suggested the States might try on remand to pursue a challenge to the Final Rule’s “overbreadth” to the extent it reached beyond “the Little Sisters and other still-objecting groups” whose “sincere religious objections” extended to both the Mandate and the accommodation. 591 U.S. at 708 (Kagan, J., concurring in the judgment). But while the States now follow suit and assert “the religious rule does not reasonably address the problem it purports to resolve” due to overbreadth, the States nowhere in their Complaint raised such a challenge to the Final Rule under the APA. Mem. 17 (emphasis and capitalization omitted); *see* Dkt. 89 ¶¶ 166-89 (basis for Administrative Procedure Act claims). No matter: the overbreadth challenge by the States fails.

First, the States insist that the exemption is available even where the “Accommodation fully resolves an entity’s religious or moral objection.” Mem. 19. That misreads the regulation. The exemption applies, and is available, only:

to the extent that an entity ... objects, based on its sincerely held religious beliefs, to its establishing, maintaining, providing, offering, or arranging for (as applicable): (i) Coverage or payments for some or all contraceptive services; or (ii) A plan, issuer, or third party administrator that provides or arranges such coverage or payments.

45 C.F.R. § 147.132(a)(2); *see id.* § 147.132(a)(1) (guideline requirements will not bind religious objectors “to the extent of the objections specified below”). Contrary to the States’ reading, an entity does not qualify for a total exemption if it “merely *objects* to contraception” but has no objection to “directly covering contraception, or complying with the Accommodation.” Mem. 18. Rather, the exemption only applies “to the extent that an entity ... objects” to compliance. 45 C.F.R. § 147.132(a)(2). An entity that had a sincere objection only to paying for a few forms of contraception and had no complicity-based objection to the accommodation would be ineligible for a complete exemption from any form of compliance with the Mandate.

The Final Rule’s explanatory text does not contradict this reading. Justice Kagan’s concurrence and the States suggest the exemption might be broader based on language that: (1) mentions that many religious nonprofit hospitals and health systems maintain “accommodated plans”; (2) notes that many of these “have publicly indicated that they do not conscientiously oppose participating in the accommodation”; and (3) indicates that “some of these religious hospitals or health systems may opt for the expanded exemption.” 83 Fed. Reg. at 57,576-77; *see Little Sisters*, 591 U.S. at 708 n.3 (Kagan, J., concurring in the judgment); *see also* Mem. 18 (citing Rule). Given the clarity of the text in the Code of Federal Regulations, this language cannot reasonably be read to allow religious hospitals or health systems that genuinely have no religious objection to the accommodation method of compliance to nevertheless avail themselves of the exemption. At most, the agencies appear to have left open the possibility that there existed “reluctant users of the accommodation” who had sincere religious objections that were due respect under RFRA, but nevertheless complied in the past. 83 Fed. Reg. at 57,574. Exempting such entities if they existed—only to the extent of their objection—would be consistent with the agencies’ reasoning and

authority, and within the category for whom Justice Kagan saw no problem.

The States also claim the Final Rules are overbroad because they allow for the possibility of a publicly traded entity obtaining a religious exemption. Mem. 19. As the States acknowledge, the Final Rules did not actually identify any publicly traded company that had ever raised an objection to the contraceptive mandate. Mem. 10 (citing J.A. 27). The States thus have no standing to raise this particular overbreadth claim, facing no reasonable possibility of traceable injury. *See supra* Part I. In any event, the Supreme Court has blessed the agencies’ ability to grant exemptions based on their best understanding of what RFRA requires in this sphere, even if no court decision yet establishes as certain the need for an exemption. *See Little Sisters*, 591 U.S. at 681-82 (noting the Court in *Zubik* “directed the parties on remand to ‘accommodat[e]’ the free exercise rights of those with complicity-based objections to the self-certification accommodation” without deciding whether that “accommodation ran afoul of RFRA”).

E. The Final Rule is severable.

Even *if* the Final Rules were overbroad in the manner the States suggest, the States never explain why the allegedly overbroad provisions cannot simply be severed, leaving the protections for groups like the Little Sisters intact. Indeed, the States’ only contention regarding severability is that the “principal defects” they claim to have identified with the Final Rules—meaning the supposed “flaws in the rationale” behind the Final Rules and their “inadequately explained change of position”—“infect the Rules in their entirety.” Mem. 44. But as explained, the Final Rules do not suffer from these defects at all, much less “in their entirety.” Because the States make no other attempt to explain why any supposedly overbroad portions of the Rules would not be severable, they should be considered to have surrendered the point. *See Hausknecht v. John Hancock Life Ins. Co. of N.Y.*, 334 F. Supp. 3d 665, 675 n.5 (E.D. Pa. 2018) (Beetlestone, J.) (contentions not included in plaintiff’s opening brief were deemed waived) (citing *Laborers Int’l Union of N. Am., AFL-CIO v. Foster Wheeler Corp.*, 26 F.3d 375, 398 (3d Cir. 1994)).

Multiple Justices have recently emphasized the “strong presumption of severability” that applies when reviewing the work of the political branches. *Barr v. Am. Ass’n of Pol. Consultants, Inc.*, 591 U.S. 610, 636 (2020) (plurality); *id.* at 648 (Breyer, J., concurring in the judgment in part and dissenting in part) (“agree[ing] ... that the provision is severable”). And even absent a strong presumption, severability is generally available where a severability clause is provided by law and severance does not disturb the other portions of the law. *Seila Law LLC v. CFPB*, 591 U.S. 197, 235 (2020) (severing “offending tenure restriction” where other portions of statute were “fully operative” and nothing “in the text or history” of the statute displaced the severability clause); *see Alaska Airlines, Inc. v. Brock*, 480 U.S. 678, 686 (1987) (“inclusion of such a [severability] clause creates a presumption” that a statute does not rise and fall with a single provision struck as unconstitutional). While the Court often confronts the severability question in the context of statutes, it has applied the doctrine equally to partially deficient regulations. *See K Mart Corp. v. Cartier, Inc.*, 486 U.S. 281, 294 (1988) (severing subsection of regulation where “[t]he severance and invalidation of this subsection will not impair the function of the statute as a whole, and there is no indication that the regulation would not have been passed but for its inclusion”) (citing *Bd. of Governors of FRS v. Dimension Fin. Corp.*, 474 U.S. 361, 368 (1986)).

Here, the regulation expressly provides a severability clause, stating both that all its provisions “shall be construed so as to continue to give maximum effect to the provision permitted by law” and that in the case of “utter invalidity” a provision “shall be severable from this section and shall not affect the remainder thereof.” 45 C.F.R. § 147.132(d). And given that the Little Sisters of the Poor and like nonprofit religious organizations were the core reason for the creation of the expanded exemption, “there is no indication that the regulation would not have been passed but for” the inclusion of other entities. *K Mart Corp.*, 486 U.S. at 294. Therefore, to the extent the Court finds the protection for “for-profit entit[ies] that [are] not closely held” to be invalid, it may and should properly sever 45 C.F.R. § 147.132(a)(1)(i)(D) without disturbing the remainder of the

regulation. Likewise, the Final Moral Exemption Rule of which the States complain—which was codified by separate rulemaking into a separate regulation with its own severability clause, *see* 45 C.F.R. § 147.133(d)—may be struck without disturbing the Final Religious Exemption Rule. The same goes for any application of the Final Rule to organizations whose sincere religious belief does not require them to make use of the exemption. As the States present no argument to the contrary, the Court need not go further.

CONCLUSION

This Court should grant summary judgment in favor of the Defendants and deny the States’ summary judgment motion. In the alternative, Defendant-Intervenor respectfully requests that, if the Court accepts the States’ arguments and invalidates the Final Rules, the Court also invalidate the regulations implementing the Mandate prior to October 13, 2017.

Dated: April 17, 2025

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CERTIFICATE OF SERVICE

I hereby certify that a copy of the foregoing document was electronically filed with the Clerk of the Court for the United States District Court for the Eastern District of Pennsylvania using the CM/ECF system, and that service will be effectuated through the CM/ECF system.

Dated: April 17, 2025

/s/ Mark Rienzi
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